UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.
09/[illegible]4	12/04/00	WALKER	D6288

HM22/0710

DR. BENJAMIN ADLER
MCGREGOR & ADLER, LLP
8011 CANDLE LANE
HOUSTON TX 77071

EXAMINER	
HAGHIGHATIAN, M	

ART UNIT	PAPER NUMBER
1619	2

DATE MAILED: 07/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/729,468	WALDREP ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite due to "increasing", which is a relative term and needs to be compared to a base, such as compared to untreated patient. Claims 1-4 are vague and indefinite due to containing a percent value with no units such as volume/volume, weight/weight, etc.

Claims 11 and 14 are vague and indefinite due to "sterically stabilized". What is meant by this term? Claim 18 is vague and indefinite due to "derivatives". Claims 23-24 are vague and indefinite because they contain "nitrogen:phosphate ratio" in polyethylenimine. Polyethylenimine does not contain phosphate.

Any remaining claims are rejected due to depending on a rejected base claim on an indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless – (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 5-6 and 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Densmore, Jr. et al (6,106,859).

'859 teaches a liposomal aerosol composition, comprising a pharmaceutical compound, a cationic lipid, a neutral composition-lipid and a tryptone. '859 discloses the use of 5% carbon dioxide in aerosolized preparations for enhancing the deep breathing of animals and thereby enhancing the lung deposition of the transfection formulations. The animal is exposed to aerosol for a period of 1minute (col. 2, lines 20-26).

Also disclosed is that animals were subjected to either intermittent aerosol exposure of the lipid:DNA (chloramphenicol acetyl transferase) formulations indicated, using a jet nebulizer, for 1 minute of aerosol followed by a 9 minute delay to allow the animals breathe the aerosol (col2, lines 55-67).

'859 teaches that the pharmaceutical compound is a gene in the form of plasmid DNA. Representative examples of useful phospholipids include phosphatidylcholine, dimyristoylphosphatidylcholine, dilaurylphosphatylcholine, dioleoyl-phosphotidylethanolamine (col.3, lines 18-37).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 4, 7 and 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Densmore, Jr. et al as applied to claims 1, 3, 5-6 and 19-22 above, and in view of Knight et al (6,090,407).

Densimore was discussed above, however it lacks teachings on drugs such as the anti-cancers.

Knight et al teaches small particle liposome or lipid complex aerosol compounds and methods of treatment, which involves lipid or water soluble anti-cancer drugs incorporated into liposomes or other lipid complexes. The liposomes and complexes Are administered in aqueous dispersions from a jet nebulizer to the respiratory tract of an individual. Various anti-cancer drugs may be used, including Camptothecin, Taxol and their derivatives (see abstract and col. 5, lines 38-40).

Knight discloses that if the drug is water soluble, it may be incorporated by appropriate procedures in aqueous vesicles in lipids, and if the drug is lipid soluble, it will associate with the lipid molecules in a manner specific to the lipid employed (col. 1, lines 12-39).

It would have been obvious to a person of ordinary skill at the time the invention was made to have modified the process of using carbon dioxide in aerosolized compositions as taught by Densmore, by adding the anti-cancer medications in an aerosol formation, as taught by Knight, with a reasonable expectations of obtaining an aerosolized composition for cancer treatment which enhances lung deposition of the actives.

Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Densmore, Jr. et al as applied to claims 1, 3, 5-6 and 19-22 above, and further in view of Waldrep et al (5,958,378).

7-01

Densmore's teachings are discussed above, and it fails to disclose some drugs useful for aerosol compositions.

Waldrep teaches high dose pharmaceutical liposome aerosol compositions. The active agents are those such as anti-inflammatory glucocorticoids, immunosupressive compounds, antifungal compounds, antibiotics, anti-virals, and anti-cancer compounds delivered via a high dose liposome aerosol composition in a phospholipid (see abstract).

It would have been obvious to a person of ordinary skill at the time the invention was made to have modified the process of using carbon dioxide in aerosolized compositions as taught by Densmore, by adding the compositions of Waldrep containing various classes of medications such as antibiotics, anti-virals, anti-cancer, etc, in an aerosol formation, with a reasonable expectations of obtaining an aerosolized

composition for variety of treatments, which enhances lung deposition of the pharmaceutical actives.

It further would have been obvious to a routineer in the art, to have optimized the amount of carbon dioxide by routine experimentation for different drugs and patients, such as children, geriatrics, patients with special disorders, etc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on MON-FRI from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
Patent Examiner

July 2, 2001

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600